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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/966,233	11/07/1997	SE-JIN LEE	241800	5193

7590

06/24/2003

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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/24/2003

#3167

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

08/966,233

Applicant(s)

LEE, SE-JIN

Examiner

Marianne P. Allen

Art Unit

1631

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 21 March 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

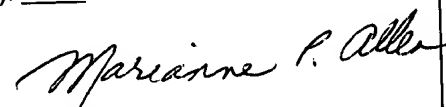
NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 1-3, 11-15 and 24-42.Claim(s) withdrawn from consideration: none.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See comments and PTO-892



Marianne P. Allen  
Primary Examiner  
Art Unit: 1631

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**EXAMINER'S COMMENTS**

It is noted that the corrected Appeal Brief was filed 5/14/03.

Appellant's brief presents arguments with respect to Akhurst et al. As set forth in the prior Office action, appellant has provided only the abstract to the examiner. Neither the abstract nor the full reference have been made of record by appellant. As such, the examiner provides the full reference for appellant and makes the reference of record. The reference discloses information about TGF- $\beta$ 1, TGF- $\beta$ 2, and TGF- $\beta$ 3 in mammalian embryogenesis. Akhurst et al. also discusses the wide variety of activities found in the larger TGF- $\beta$  superfamily. Page 155 states, "As yet there is no definitive evidence that any of the TGF $\beta$ s are endogenous regulators of mammalian embryonic processes." It is emphasized by the examiner that what is under discussion here is TGF- $\beta$  itself and not the larger superfamily. Thus, this reference provides no evidence with respect to the proteins of the larger superfamily and their role in mammalian embryogenesis. Appellant is reminded that the protein disclosed to have the highest homology to GDF-1 was not TGF- $\beta$ 1, TGF- $\beta$ 2, or TGF- $\beta$ 3, but rather Vg-1 which is from amphibians and not mammals. The totality of Akhurst et al. fairly indicates that those of skill in the art at the time of the invention were experimenting and looking to see whether TGF- $\beta$ 1, TGF- $\beta$ 2, and TGF- $\beta$ 3 proteins were involved in mammalian embryogenesis and how. The conclusion and prospects section of the reference on pages 164-165 states that the evidence would suggest that each isoform of TGF- $\beta$  (i.e. TGF- $\beta$ 1, TGF- $\beta$ 2, and TGF- $\beta$ 3) has a distinct function *in vivo*. The reference states, "To test this proposition, it is essential that more functional studies are carried out." This supports the examiner's position that further research would be required to reasonably determine or confirm any activity or involvement of GDF-1 in embryogenesis. Furthermore, the reference amply illustrates that embryogenesis is a highly diverse and complex process including skeletal development, hematopoiesis, vascularization, and so forth. (See pages 157-164.) This is also acknowledged by the specification as filed on page 2, lines 15-20. As such, a disclosure that GDF-1 may be involved in embryogenesis cannot be considered to convey to those of ordinary skill in the art any specific or clear biological activity. It provides no direction or guidance as to which aspect or to a particular activity.

In addition, appellant's brief presents arguments with respect to Rankin et al. The reference was not made of record by appellant. As such, the examiner also includes this reference on the PTO-892. A copy was provided by appellant previously.